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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,921	10/27/2003	Fujio Suzuki	SHX 332	5097

23581 7590 07/11/2006

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,921

Applicant(s)

SUZUKI ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/16/04, 8/16/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The specification appears to missing the required section entitled Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-4 are rejected under 35 U.S.C. 101 because they are- drawn to non-statutory matter. The claimed recitation of a process, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-4 are drawn to the use of a compound of formula (I) in the induction of RANTES, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 1-4 are therefore rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 5 and 6 are rejected under 35 U.S.C. 102(B) as being anticipated by Suzuki et al, The Induction Of β -chemokines By Glycyrrhizin (GR), An Active Component Of Licorice Roots, in Cultures of Peripheral Blood Mononuclear Cells, Journal Of Allergy And Clinical Immunology, Vol. 105, No. 1, Part 2, January 2000, page S113). Suzuki discloses (Paragraph 339, column 2, lines 25-26) that treatment with pharmaceutical compositions of Glycyrrhizin (GR), a compound of formula (I), causes both CD4⁺ and CD8⁺ T cells to produce RANTES. Suzuki further discloses

(Paragraph 339, column 2, lines 27-32) (Paragraph 339, column 2, lines 25-26) the treatment of HIV infection with GR. Suzuki therefore anticipates claims 5 and 6.

5. Claims 5 and 6 are rejected under 35 U.S.C. 102(B) as being anticipated by Utsunomiya et al (Clinical and Experimental Immunology, Effects of Glycyrrhizin, an Active Component of Licorice Roots, on Candida Albicans Infection in Thermally Injured Mice, Oxford, GB, Vol. 116, No. 2, May 1999, Pages 291-298) as illuminated by Suzuki et al, The Induction Of β -chemokines By Glycyrrhizin (GR), An Active Component Of Licorice Roots, in Cultures of Peripheral Blood Mononuclear Cells, Journal Of Allergy And Clinical Immunology, Vol. 105, No. 1, Part 2, January 2000, page S113). Utsunomiya discloses (Page 296, column 2, 2nd full paragraph) the protective effect of treatment of immunocompromised (burned) mice with pharmaceutical compositions containing glycyrrhizin (GR), a compound of formula (I), against infection by *C. albicans*. The Examiner notes that this treatment inherently induces the production of RANTES as illuminated (Paragraph 339, column 2, lines 25-26) by Suzuki.

Claim Objections

6. Claims 5 and 6 are objected to as depending upon non-statutory claims 1-4. Applicant should amend claims 5 and 6 to include the required limitations of the non-statutory claims. Appropriate correction is required.
7. Claim 6 is objected to because of the following informalities: Claim 6 recites the phrase "comprising : containing" in line 1. Appropriate correction is required.


Conclusion

8. Claims 1-6 are pending Claims 1-6 are rejected. Claims 5 and 6 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PAUL A. ZUCKER, PH.D.
PRIMARY EXAMINER
